JUN - 3 2003

K024344

Airon

**Pneuton Ventilator**

**510(k) Summary**

**Contact Information**
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**Application Date**
December 26, 2002

**Device Trade Name**
Pneuton Ventilator

**Common Name**
Transport ventilator

**Device Classification**
Continuous Ventilator (21 CFR 868.5895, Classification number 73 CBK)

**Device Class**
Class II

**Classification Panel**
Anesthesiology

**Predicate Devices**
Pneupac 2-R Ventilator
- manufactured by Pneupac Ltd
- 510(k) number K862830
- currently marketed through Pneupac USA as the paraPAC Responder Ventilator

IC-2A MRI Ventilator
- manufactured by Bio-Med Devices
- FDA 510(k) number K896380

**Device Description**
Pneuton (pronounced "new-ton") is a small, lightweight transport ventilator designed for use on patients from pediatric to adult in size (10 kg and higher). It is a time cycled, flow limited ventilator providing Continuous Mechanical Ventilation (CMV) or Intermittent Mandatory Ventilation (IMV). In these modes of ventilation, an adjustable respiratory rate and tidal volume are delivered to the patient. The patient is allowed to breath spontaneously between the mandatory breaths with little added work of breathing. A built-in PEEP / CPAP system can be set to provide expiratory positive pressure. The delivered oxygen is adjustable at 65 or 100 percent.

Pneuton is a pneumatic ventilator. Electrical power is not required for patient ventilation. The pneumatic system operates at input pressures from 41 to over 66 psi. Various control systems manage the tidal volume and rate control, PEEP / CPAP, and safety systems / pneumatic alarms.

The Pneuton Ventilator uses accessories for normal operation which are included with this submission. The primary accessory is a patient tubing circuit to attach the ventilator to the patient. The patient circuit is a class 1 device, currently exempt from premarket notification. The patient circuit is a disposable device, not to be sterilized or disinfected (see section 12 of this submission). Additional accessories will be sold with the device including travel case, pole stand and mounting brackets.

**Intended Use**
The device is intended for continuous or intermittent mechanical ventilator support for the care of individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified medical personnel under the direction of a physician.

Specifically, the ventilator is applicable for adult and pediatric patients, 23 kg (50 lbs.) and greater who require the following general types of ventilatory support:
- positive pressure ventilation delivered invasively (via an ET Tube) or non-invasively (via a mask)
- CMV and IMV modes of ventilation
- with or without PEEP / CPAP
- with oxygen or a mixture of air and oxygen

The ventilator is suitable for use in:
- Pre-hospital transport applications including accident scene, emergency rescue vehicles
- Hospital ICU and transport applications including emergency, radiology, surgery, recovery and MRI departments
- Air transport via helicopter or fixed wing

**Substantial Equivalence**
The Pneuton Ventilator shares substantial equivalency with the Pneupac Ltd. Pneupac 2-R Ventilator and the Bio-Med Devices IC-2A MRI across the spectrum of patient population for which each was designed. All of the devices share common modalities

(CMV, IMV, PEEP / CPAP) and significantly overlap in the clinical range of function for their target population. The essential clinical function of each device is significantly similar and mimics each other in the typical frame of use by the health care provider. Each are pneumatic controlled and applicable for the same areas of use.

| Characteristic | Pneuton | 2-R | IC-2A | Discussion |
|---|---|---|---|---|
| Operating principle | Pneumatic | Pneumatic | Pneumatic | Equivalent |
| Input gas pressure | 40 to 70 psi | 37 to 87 psi | 45 to 55 psi | Substantially equivalent |
| Patient circuit | Standard with external expiratory valve | Special with external expiratory valve | Standard with external expiratory valve | Equivalent |
| Enclosure | Rugged, lightweight | Rugged, lightweight | Rugged, lightweight | Equivalent |
| Displays | Manometer | None | Manometer | Pneuton and IC-2A are equivalent |
| Alarms | Low gas source | None | None | Pneuton only device with alarm |
| Modes of ventilation | CMV, IMV, CPAP | CMV, PEEP | CMV, SIMV, CPAP | Substantially equivalent |
| Tidal volume | 360 - 1500 | 340 - 1450 | 0 - 3000 | Pneuton and 2-R are equivalent |
| Respiratory rate | 2 - 50 | 11 - 21 | 1 - 66 | Pneuton and IC-2A are equivalent |
| Flow | 36 | 40 | 0 - 75 | Pneuton and 2-R are equivalent |
| PEEP / CPAP | 0 - 20 | external | 0 – 25 | Pneuton and IC-2A are equivalent |
| Peak pressure | 10 - 75 | 40 or 60 pre-set | 0 – 75 | Pneuton and IC-2A are equivalent |
| I : E ratio | Continuously adjustable | 1:1.5 to 1:5 based on setting of volume / rate control | Continuously adjustable | Pneuton and IC-2A are equivalent |
| Internal oxygen control | 2 position, 100% or 65% | External | External | Pneuton only unit with internal oxygen mixing |

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**Summary of Non-Clinical Testing and Validation**
The performance of the Pneuton has been comprehensively tested. All functions as listed in the specifications have been validated. The ventilator meets all test requirements as identified in the FDA Reviewer Guidance for Ventilators.

The Pneuton complies with the following standards:

- ASTM F 1100-90 Ventilators Intended for Use in Critical Care
- Minimum requirements for Automatic Transport Ventilators as described in the Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care from the American Heart Association (AHA), pages 2200 and 2201 JAMA, October 28, 1992 - Vol 268, No.16.
- MIL STD 810 E Test Method Standard for Environmental Engineering Considerations and Laboratory Tests
- ISO 10651-3 Lung Ventilators for Medical Use. Particular requirements for emergency and transport ventilators

Clinical testing was not performed on this device. Safety and efficacy were established through non-clinical testing. The Pneuton performs as intended according to it's performance specification. The Pneuton is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. G. Eric Gjerde
President
Airon Corporation
102 East New Haven Avenue, Suite 146
Melbourne, Florida 32901

Re: K024344
Trade/Device Name: Pneuton Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 17, 2003
Received: April 18, 2003

Dear Mr. Gjerde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number K024344

Device Name: Pneuton Ventilator

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K024344

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)